

SUMMARY SHEET

Subject: Recommendations Regarding Disclosure to Patients Injected with Plutonium during and after World War II

Purpose: To inform the Commission of recommendations made by the Director of DBER and the Office of the General Counsel relative to the disclosure to patients of the nature of the injections and of ongoing investigations conducted on them *patients.*

Discussion: Eighteen patients were injected with tracer doses of plutonium in four hospitals in Rochester, Chicago, San Francisco and Oak Ridge in 1945-1947 to investigate the metabolism and excretion of plutonium. Studies by AEC contractors were conducted on the patients for up to five years after injection and, more recently, since January 1973. In at least some cases, including those now under study, the nature of the injections and the purpose of the studies have not been disclosed to the patients. DBER is recommending that the physicians conducting the investigations either provide disclosure to the patients in accordance with DHEW policy on the protection of human subjects or provide the AEC with a statement that the appropriate committee of the University *of Rochester* or of Argonne National Laboratory concerned with insuring compliance with DHEW policy have reviewed the matters in detail and taken the appropriate actions. AEC requires its contractors to adhere to DHEW policy in carrying out such investigations.

Coordination: The enclosed report was coordinated with lead Commissioner Ray and the Office of the General Counsel.

1. Soon after the initial preparation of sizable quantities of plutonium, ~~the potential for exposure of many workers~~ ^{a decision} was made by the Manhattan Engineering Project to investigate the metabolism and excretion of plutonium in man. The studies involved injection of eighteen hospital patients with tracer doses of plutonium during 1945-1947. Although the patients were considered at that time to be near terminal, in several instances their medical conditions proved to be compatible with a much longer survival than anticipated.

In a joint effort of the Los Alamos Scientific Laboratory and the Atomic Energy Project of the University of Rochester School of Medicine and Dentistry, eleven patients were injected at Strong Memorial Hospital in Rochester and one at the Oak Ridge Hospital. In additional studies, three patients were injected at the Billings Hospital in Chicago and three at the University of California Hospital in San Francisco. It is likely that all were injected intravenously except one patient with a malignant bone tumor in a leg; in the latter case the injection was made into a leg muscle four days before amputation.

2. A lengthy chapter, written by Dr. Patricia W. Durbin of Lawrence Berkeley Laboratory in the monograph, "Radiobiology of Plutonium," reviewed the scientific studies that had been completed earlier on the above cases. The report, which appeared in 1972, presented essential clinical information on the patients and data relative to the injections. Earlier reports had appeared largely in publications of the relevant laboratories.

3. The scientific studies were continued after injection on a progressively diminishing scale by AEC contractors on some patients for as

long as five years but were then interrupted until 1973. In December 1972, the accumulated records of the investigations, which were then in the possession of Dr. Durbin, were transferred to Dr. R. E. Rowland at the Center for Human Radiobiology in Argonne National Laboratory. At that time four patients had survived; the four are still alive. Arrangements were made by Dr. Rowland to have metabolic studies conducted on three patients at Rochester. The fourth was contacted but refused examination. Clinical examinations and the collection of excreta were performed on the metabolic ward at Strong Memorial Hospital in Rochester; the specimens were analyzed for plutonium content at Argonne and LASL. One patient had both a physical examination and radioactivity measurements at Argonne in addition to a medical workup in Rochester. The recent examinations were performed between January and June 1973. In addition, Dr. Rowland obtained permission for exhumation of the body of an injected patient who had expired two years after injection. Studies on the remains have been carried out since the exhumation in September 1973.

4. It is our understanding that the nature of the injections and of the ongoing studies has not been disclosed to those patients who have survived nor, probably, to others who were injected. In accordance with DHEW recommendations as stated in "The Institutional Guide to DHEW Policy on Protection of Human Subjects," informed consent of the subjects is required in all such investigations. Furthermore, the review and approval of such projects by a Human Use Committee in advance of the initiation of investigational activities is necessary. AEC requires its contractors to adhere to DHEW policy in these matters. In view of the participation of Argonne National

Laboratory in the above studies, both directly and through funding of the activities at Strong Memorial Hospital, DBER is recommending early compliance with disclosure requirements by the physicians involved in these investigations. It is recognized that the disclosure must be conducted in such a manner that the physician-patient relationship is not violated and the welfare of the patients is safeguarded. Nevertheless, the obligation to provide disclosure in a manner appropriate to the prevailing circumstances needs to be fulfilled.

RECOMMENDATION

It is the strong recommendation of the Director of DBER and of the General Counsel that the Director of DBER proceed immediately to inform the Argonne National Laboratory of the need to comply with the DHEW recommendations and that they should proceed to bring this matter before their own or the University of Rochester Human Use Committee for disposition as that Committee may judge appropriate and to inform the Commission of ^{that} the disposition.

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